



IDS/ #3
J 8.8.02
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Henry J. WINDLE et al.

Group Art Unit: 1645

Serial No.: 10/068,870

Examiner: Unassigned

Filed: February 11, 2002

For: CLOSTRIDIUM DIFFICILE VACCINE

INFORMATION DISCLOSURE STATEMENT

RECEIVED
MAY 10 2002
TECH CENTER 1600/2900

Commissioner of Patents
Washington, DC 20231

Sir:

As a means of complying with the duty of disclosure under 37 CFR §1.56, and in accordance with 37 CFR §§1.97 and 1.98, Applicant(s), through the undersigned attorney, submits this Information Disclosure Statement. The patents, publications or other information submitted herewith are listed on the attached Form PTO-1449 and copies are attached.

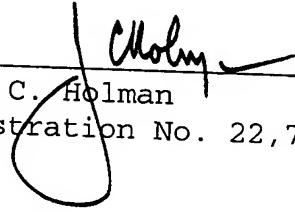
In accordance with 37 CFR §1.97(b)(1) or (2), this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, or within three months of the date of entry into the national stage of the

above-identified application as set forth in 37 CFR §1.491.
Accordingly, no fee is required.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By: _____


John C. Holman
Registration No. 22,769

400 Seventh Street, N.W.
Washington, DC 20004
(202) 638-6666
Atty. Dkt. No.: 11472/P67635US0
Date: May 9, 2002

RECEIVED
MAY 10 2002
TECH CENTER 1600/2900

JACOBSON HOLMAN PLLC
 400 SEVENTH STREET, N.W.
 WASHINGTON, D.C. 20004-2201

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.: P67635US0 GROUP ART UNIT: 1645
 SERIAL NO.: 10/068,870 FILING DATE: February 11, 2002
 APPLICANT(S): Henry J. WINDLE et al. TODAY'S DATE: May 9, 2002

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE If Appropriate)
AA						
AB						

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES) (NO)
AC					
AD					

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

____ / AE Emanuela CALABI et al., "Molecular Characterization of the Surface Layer Proetins from Clostridium Difficile", Mol. Microbiol., (2001), Vol. 40, pages 1187-1199.

____ / AF Marina CERQUETTI et al., "Characterization of Surface Layer Proteins from Different Clostridium Difficile Clinical Isolates", Microbial Pathogenesis, (2000), Vol. 28, pages 363-372.

____ / AG S.H. CHENG et al, "Clostridium Difficile-Associated Diseases: Comparison of Symptomatic Infection Versus Carriage on the Basis of Risk Factors, Toxin Production, and Genotyping Results", Clin. Infect. Dis., (1997), Vol. 25, pages 157-158.

____ / AH Michel DELMEE et al., "Comparison of Serogrouping and Polyacrylamide Gel Electrophoresis for Typing Clostridium Difficile", J. Clin. Microbiol, (1986), Vol. 24, No. 6, pages 991-994.

EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

RECEIVED

MAY 10 2002

TECH CENTER 1600/2900

JACOBSON HOLMAN PLLC

400 SEVENTH STREET, N.W.

WASHINGTON, D.C. 20004-2201

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.: P67635US0 GROUP ART UNIT: 1645
 SERIAL NO.: 10/068,870 FILING DATE: February 11, 2002
 APPLICANT(S): Henry J. WINDLE et al. TODAY'S DATE: May 9, 2002

 OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AI- Michel DELMEE et al., "Characterization of Flagella of Clostridium Difficile and Their Role in Serogrouping Reactions", Journal of Clinical Microbiology, (1990), Vol. 28, No. 10, pages 2210-2214.

AJ- Tuomo KARJALAINEN et al., "Molecular and Genomic Analysis of Genes Encoding Surface-Anchored Proteins from Clostridium Difficile", Infection and Immunity, (2001), Vol. 69, No. 5, pages 3442-3446.

AK- Tomio KAWATA et al., "Demonstration and Preliminary Characterization of a Regular Array in the Cell Wall of Clostridium Difficile", FEMS Microbiology Letters, (1984), Vol. 24, pages 323-328.

AL- C.P. Kelly, et al., "Clostridium Difficile Colitis", New England Journal of Medicine, (1994), Vol. 330, No. 4, pages 257-262.

AM- Lorraine KYNE et al., "Asymptomatic Carriage of Clostridium Difficile and Serum Levels of IgG Antibody Against Toxin A", The New England Journal of Medicine, (2000), Vol. 342, No. 6, pages 390-396.

AN- Donald Y. M. LEUNG et al., "Treatment with Intravenously Administered Gamma Globulin of Chronic Relapsing Colitis Induced by Clostridium Difficile Toxin", J. Pediatr, (1991), pages 633-637.

AO- Lynne V. MCFARLAND et al., "Correlation of Immunoblot Type, Enterotoxin Production, and Cytotoxin Production with Clinical Manifestations of Clostridium Difficile Infection in a Cohort of Hospitalized Patients", Infection and Immunity, (1991), Vol. 59, No. 7, pages 2456-2462.

AP- Maury Ellis MULLIGAN et al., "Elevated Levels of Serum Immunoglobulins in Asymptomatic Carriers of Clostridium Difficile", Clin Infect. Dis., (1993), 16(Suppl 4), pages S239-244.

EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s)

RECEIVED

MAY 10 2002

TECH CENTER 1600/2000

JACOBSON HOLMAN PLLC
 400 SEVENTH STREET, N.W.
 WASHINGTON, D.C. 20004-2201

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.: P67635US0 GROUP ART UNIT: 1645
 SERIAL NO.: 10/068,870 FILING DATE: February 11, 2002
 APPLICANT(S): Henry J. WINDLE et al. TODAY'S DATE: May 9, 2002

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

- AQ- Henrik NIELSEN et al., "Identification of Prokaryotic and Eukaryotic Signal Peptides and Prediction of their Cleavage Sites", Protein Engineering, (1997), Vol. 10, No. 1, pages 1-6.
 AR- G.L. O'NEILL et al., "Modification of a PCR Ribotyping Method for Application as a Routine Typing Scheme for Clostridium Difficile", Anaerobe, (1996), Vol. 2, pages 205-209.
 AS- Annalisa PANTOSTI et al., "Immunoblot Analysis of Serum Immunoglobulin G Response to Surface Proteins of Clostridium Difficile in Patients with Antibiotic-Associated Diarrhea", Journal of Clinical Microbiology, (1989), Vol. 27, No. 11, pages 2594-2597.
 AT- D.H. PERLMUTTER et al., "Chronic Diarrhea Associated with Hypogammaglobulinemia and Enteropathy in Infants and Children", Digestive Diseases and Sciences, (1985), Vol. 30, No. 12, pages 1149-1155.
 AU- Ian R. POXTON et al., "Variation in the Cell Surface Proteins of Clostridium Difficile", Anaerobe, (1999), Vol. 5, pages 213-215.
 AV- Janet K. SHIM et al., "Primary Symptomless Colonisation by Clostridium Difficile and Decreased Risk of Subsequent Diarrhoea", The Lancet, (1998), Vol. 351, pages 633-636.
 AW- U.B. SLEYTR et al., "Crystalline Bacterial Cell Surface Layers", Molecular Microbiology, (1993), Vol. 10, No. 5, pages 911-916.

EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s)

RECEIVED

MAY 10 2002

TECH CENTER 1600/2000